Background: Informed consent forms should document and reflect the goals of informed consent and shared decision making. We conducted this study to examine the extent to which informed consent for procedure forms meet accepted informed consent standards, how well state informed consent statutes correlate with these standards, and whether existing forms can enhance the interactions between patients and physicians or other health care providers.

Hypothesis: Informed consent forms do not meet accepted standards. A different format may be more useful for patient-physician interactions.

Design: A content analysis was conducted of hospital informed consent for procedure forms from a random selection of hospitals in the 1994 American Hospital Association membership directory. Forms were examined for evidence of the basic elements of informed consent (nature of the procedure, risks, benefits, and alternatives) and items that might enhance patient-physician interactions and encourage shared decision making.

Unit of Analysis: From 157 hospitals nationwide, 540 hospital informed consent for procedure forms were examined.

Measurements and Main Results: Ninety-six percent of forms indicated the nature of the procedure, but risks, benefits, and alternatives were found less often. Only 26% of forms included all 4 basic elements, 35% included 3 of 4 elements, 23% had 2 of 4 elements, 14% had only 1 element, and 2% had none of the elements. Forms appear to authorize treatment (75%) or protect hospitals and caregivers from liability (59%) rather than clarify information about procedures (40%) or aid patients in decision making (14%). Forms from states with statutes that require that all 4 elements be provided were no more likely than other states to include them (Fisher exact test = 1.000). Fewer than 40% of forms supported models of shared decision making.

Conclusions: The content of most forms did not meet accepted standards of informed consent or patient-physician interactions. We propose a form that more fully supports the models of ideal informed consent and shared decision making to enhance the applicability of informed consent in the clinical setting.

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In this turbulent environment of changing health care delivery structures, and with new decisions involving genetic medicine on the horizon, informed consent will be a critical element in the provision of appropriate treatment information and quality medical decision making. The informed consent process is intended to protect patients and to promote an enlightened ethic in patient-physician relationships. Legal doctrine, including hospital accreditation standards, ethical theories, and contemporary understandings of the patient-physician relationship, all underscore the importance of full patient comprehension as a means to support patient autonomy.

Minimum requirements for informed consent are well defined. In addition to the patient having the capacity to understand relevant information and make a decision, ethicists have identified 4 content elements of informed consent. At a minimum, patients should receive information regarding (1) nature of the procedure, including whether it is diagnostic or therapeutic; (2) risks involved, especially those that are severe and likely to occur; (3) benefits of the procedure; and (4) alternatives to the procedure, along with their risks and benefits. Regulatory groups, such as the Joint Commission on Accreditation of Healthcare Organizations, and some state statutes require that this information be given to patients in the process of decision making or in informed consent forms.

Despite fairly consistent agreement in the literature about the importance of informed consent and empirical research indicating that patients rely on physicians to advise them when making decisions, physicians often fail to disclose even major side effects of treatments. Physicians also often fail to provide the other elements of informed consent.
MATERIALS AND METHODS

INSTRUMENT DEVELOPMENT

We compiled a list of desirable and essential content areas in informed consent based on requirements of the Joint Commission on Accreditation of Healthcare Organizations, state informed consent statute requirements, and commonly accepted professional standards. We refined the list in consultation with a surgeon-ethicist. Additional elements relevant to shared decision making and precedent-setting legal cases were also suggested.

Nine key content areas were identified: nature of the procedure, risks, benefits, alternatives, purpose of the form, quality of the patient’s consent, level of voluntariness, interaction and process-related aspects, and other general format features. A tenth feature, deliberative agreement, was also added. Deliberative agreement is a process grounded in a progressive model of informed consent proposed by one of us (L.L.E.). It is based on a theory of structured deliberation and an idealized interactive process for shared decision making.

An instrument for data collection and content analysis was developed consisting of 63 specific items. Most items had either a yes/no indicator of the presence or absence of the specific element or a categorization of how the item appeared in the form. Possible categories were “mentioned,” “described,” or “space available to describe.” For example, appearance of the word risk or the word consequence in reference to a procedure qualified as “mentioned” in the “General Risks” category. If further information was included, eg, which patients encounter informed consent forms, the content of informed consent forms has rarely been studied. The few available studies only examine forms from a small number of hospitals or for a specific purpose.

Our study had 3 objectives: to determine the purpose of and what information is included in informed consent for procedure forms; to examine the extent to which the forms meet accepted medical, ethical, and legal standards; and to explore whether existing forms are capable of enhancing interactions between patients and physicians or other health care providers. We also suggest a new informed consent format, developed by one of us (L.L.E.), called the “Medical Decision Worksheet” (Appendix), which addresses both content-based and stylistic criticisms of current forms. Since competence to make an informed decision is a prerequisite for shared decision making, this study’s focus also addressed relevant elements of shared decision making such as interactivity and voluntariness.

RESULTS

SAMPLE

Of the 230 hospitals originally selected, 213 were eligible for the study: 14 hospitals (mostly psychiatric facilities) did not perform invasive procedures, 1 hospital had closed, and 2 hospitals did not use any informed consent forms. After up to 4 reminders by mail or tele-
EXAMINATION OF STATE STATUTES

Since differences in state statutes pertaining to informed consent might affect the content of the forms, we examined the statutes of all 28 states that have specific language related to informed consent. The statutes were coded for the presence of each specific item related to the 4 basic elements of informed consent, whether mentioned or required of forms or informed consent conversations within the state. Each state statute was classified as to whether it required "none," "some (1-3)," or "all (4)" of these elements.

SAMPLE

We randomly selected 230 hospitals from the American Hospital Association's 1994 comprehensive national membership list. A letter was sent to the director of medical records explaining the purpose of the study and requesting copies of all informed consent forms for medical and surgical procedures and interventions used by the hospital. The admitting or surgical departments were contacted to obtain forms when the medical records department was unable to provide them. Forms regarding oral consent for medical treatment were not sought. Administrative forms (eg, for admission, discharge, release of medical information, disposal of body parts, or leaving against medical advice) were excluded from analysis because they were not primarily concerned with basic treatment decisions. Research consent forms were not included in the study due to their different requirements. Nonresponding hospitals were recontacted up to 4 times through mail and/or telephone reminders.

ANALYSIS

Forms and state statutes were independently coded by 2 trained reviewers (M.M.B. and H.A.). Interrater reliability using k statistics and percentage agreement between the 2 coders were calculated on a random sample of 80 informed consent forms and on all 28 state statutes. The weighted frequencies of each response type for each item were computed over all forms. Weighting was inversely proportional to the numbers of forms received per hospital so that the results would not be biased toward hospitals that provided more forms than others. For example, frequencies from hospitals providing 4 forms were weighted by a factor of 0.25. Contingency table analyses and the chi² statistic were used to compare frequencies of content elements between forms of various types and from various sources.

RISKS, BENEFITS, AND ALTERNATIVES

Table 1 lists the frequency of inclusion of risks, benefits, alternatives, and other important features of the procedure. While 87.1% of the forms noted the general possibility of risks, fewer forms provided further specific information, such as which serious risks were possible (45.9%), the probability of the risk occurring (14.6%), or how soon after the procedure a risk or side effect might occur (3.3%). Benefits were referred to less often (37.0%) than alternatives to the procedure (56.9%). Specific information about both benefits and risks was rarely noted.

PURPOSES OF THE FORM

Forms were most commonly considered to be for purposes of treatment authorization (74.6%) or to protect against liability (38.7%). Forty percent of forms appeared to be for the purpose of clarifying information about the procedure, 13.9% had a stated purpose for aiding patients in decision making, and 18.8% referred to nonclinical issues, such as disposal methods for removed body parts. Phrases such as, "I certify that no guarantee or assurance has been made as to the results that may be obtained," and "I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me as to the results of treatments or examinations performed in this hospital," were common. A few forms included statements indicating that the purpose of the form was
for patient information. In these instances, the forms included statements such as, “You have the right . . . to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.”

**BASIC ELEMENTS OF INFORMED CONSENT**

Only 26.4% of forms included all 4 of the accepted basic elements of informed consent, 34.8% included 3 of 4 elements, 22.7% had 2 of 4 elements, 13.8% had only 1 element, and 2.4% included none of the required elements (data not shown). Forms from the states that required “all” 4 basic elements be provided to patients during informed consent discussions (n = 7) were no more likely to include information beyond risks than forms from states requiring “some” (n = 12) or “none” (n = 9) of the elements (Fisher exact test = 1.000), nor were they more likely to mention elements of structured deliberation than forms in other states ($\chi^2 = 1.48$, $P = .22$).

**FACILITATING PATIENT-PHYSICIAN INTERACTIONS**

Information that would indicate the level of voluntariness and interaction between patient and physician was found in the forms to varying degrees (Table 2). For example, a signature indicating that the patient understands the information provided was found in 54.1% of the forms, a statement that the patient has a right to refuse the treatment even after signing the form was found in 9.6% of forms, prompts for the physician to sign the form in 1.9% and for the nurse in 23.0%, identification of how to obtain further information in 12.4%, and what the patient could do if he or she did not understand the information in 7.0%.

**STRUCTURED DELIBERATION**

Two elements of structured deliberation, “content exploration/information transmittal” (29.4%) and “limit setting” (22.6%) were noted most often, while the remaining elements were rarely if ever seen (data not shown are available from the authors).

**COMMENT**

Examination of these 540 informed consent forms demonstrates that forms as designed have limited value: they are constructed to authorize treatment or to document an action pertaining to informed consent, regardless of whether the informed consent process was successfully accomplished or of minimal quality. Such a construc-
tion may even reduce the likelihood of a quality informed consent process by increasing the perception of physician or institutional self-protection over patient care, and causing patient anxiety and annoyance from having to sign another piece of paper. Yet, the substance of forms includes little information that could, by itself, protect physicians or hospitals in the event of a lawsuit questioning the content of the informed consent discussion, much less protect patient autonomy and ensure truly informed consent.

Despite research demonstrating that patients who receive written information about their procedure generally have better understanding and higher recall regarding their procedures, our analysis demonstrates that the informed consent forms currently in use provide little substantive content to help patients make decisions, or even meet basic standards for informed consent. While nearly all forms included at least 1 of the 4 elements, that element was most often only in the name of the procedure, without a description. Risks, the element most emphasized in the informed consent literature, were not even mentioned in 13% of the forms. Even fewer forms included information about treatment benefits, alternatives, or other information that would help patients understand the procedure, such as descriptions of risks or prognosis, or explanations of types of benefits that could be expected (Table 1).

Many authors point out that the appropriate way to conduct an informed consent discussion is through “active patient participation in the choice among plausible alternatives.” Lidz et al offer their process model of informed consent, which requires considered, ongoing discussion between patient and physician at every step of treatment. The technique of structured deliberation, based on similar principles, seeks to improve discussions about medical care decisions by encouraging patients and physicians to work through a structured process. It involves 5 intermingling components: first is permission and orientation, inviting patients to discuss the topic and relevant personal and cultural norms, and so identifying the issues and approaches acceptable to them. Second is structuring information in forms that are tailored to the patient. Third is the content of deliberation, which fosters and facilitates patient self-understanding as well as information use. Fourth is the process of reflection, which allows the patient to bring together all of the issues and come to stable resolution. Finally is commitment to the chosen decision.

Informed consent forms could facilitate the patient-physician dialogue, whether based on the above models or a different one, by providing structure and “talking points” to encourage personalized, comprehensive discussions that are tailored to the patient’s concerns rather than to the legal needs of physicians or hospitals. Studies comparing attitudes of patients who received information through a structured interview vs those who had an informal interview that reflected current informed consent practice have revealed positive outcomes for patients. Patients who underwent a structured interview felt less obliged to sign the consent form, were more likely to feel involved in the treatment decision, and were less likely to consider the interview a formality. Thus, forms that use a structured discussion format may be more likely to achieve ideal informed consent than the forms cur-
rently used. No form can guarantee an adequate discussion between the patient and the physician, but the ideal form can facilitate a clear and comprehensive discussion between both parties.

A WORKSHEET FOR DELIBERATIVE AGREEMENT

It is important not to leave a study like this without exploring possible solutions that may be indicated by the findings. Accordingly, we propose a possible new format for informed consent forms, the Medical Decision Worksheet (the worksheet) (Appendix).

The worksheet provides basic “talking points” to lead a patient-clinician dyad through the informed consent decision-making process with a full discussion of the relevant issues. Besides providing space for including the basic elements of informed consent, the worksheet encourages full description of these elements and their context. A common argument against informed consent is the impossibility of noting all potential outcomes and side effects. The worksheet reminds the physician to explain the context of choices and risks in a fashion that, while necessarily not exhaustive, should maximize the potential for patients to fully understand and participate in the decision. It can then be used to document the informed consent process if so desired.

The worksheet encourages partnership in the process of making medical decisions. It makes explicit the physician’s role—to provide information to the patient, to outline the quality and content parameters of that information, and to participate in the process of determining an appropriate treatment plan (Table 2). We envision the patients and clinicians using the worksheet as a “notepad,” with both parties discussing the issues and writing down relevant points on it. Actively sharing a worksheet can symbolically, as well as actually, promote the interaction process. Oriented to the physician rather than other health care providers to emphasize the physician’s obligation to be involved, the worksheet could nonetheless be used by other members of the interdisciplinary care team. Supportive assistance from other care professionals is to be welcomed as noted in the mental checklists of desirable items.

The worksheet has other features. It goes further than most consent forms to solicit and acknowledge each patient’s different values and methods of decision making by leading the patient through a process of structured deliberation. For physicians not fluent in the patient’s primary language, this structure could also guide physicians to identify the issues that must be translated. The worksheet’s framework could also function as a screen to ensure that a patient has the capacity to make a medical decision. Simply reading and signing a traditional informed consent form does not necessarily ensure that the patient is competent; however, successful completion of the process of structured deliberation inherent in the worksheet demands the patient’s ability to participate with understanding and judgment.

To realize the full potential of the worksheet or any consent form, a number of implementation issues will have to be resolved. First, physicians may need better instruction in the use of the process, including use of the forms. Further, more knowledge of the optimal timing of informed consent discussions would assist in the integration of forms into the decision-making process. Finally, appropriate conduct of informed consent discussions are a function of interactions between patients and physicians, the culture of the family and of medicine, and other factors. Thus, further research is key to improving the whole informed consent process.

CONCLUSIONS

Our analysis demonstrates that existing forms are inadequate for demonstrating legal or ethical standards for informed consent. Nor do existing forms facilitate the informed consent process; they may hinder it. A form such as the Medical Decision Worksheet that focuses on the substance and process of the interaction may be more useful for patient-physician interactions, and possibly also for liability risk purposes. It is hoped that our proposal will stimulate further discussion about ways to improve the informed consent process and further empirical research on new forms.


We thank Lynn Peterson, MD, for consultation regarding instrument development and Gloria Ramsey, RN, JD, Marty Mezy, RN, EdD, and Adam Rogers for their thoughtful comments.

The Medical Decision Worksheet is the sole property of Dr Emanuel, not the other authors of this study. Copies of the worksheet may be obtained from her at the address given below.

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REFERENCES


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Appendix. The Medical Decision Worksheet

What Is This Worksheet?
This is a worksheet to help you think through your medical decision. It is best used as part of a discussion with your physician and other health care professionals, family members, or friends. You and your physician or other health care professionals can fill it in together. This worksheet, when completed, can be signed and used to record your decision.

What Is Informed Consent and Deliberative Agreement?
Good medical decisions usually need some teamwork. Your physician gives you all the relevant information you want about the decision for your care. Then you decide whether or not to agree to the decision. If you agree, that is your informed consent.

Deliberative agreement is a process of discussion that ends in agreement about what to do. It includes informed consent but also involves more talking and advising. You tell your physician how much you want to be involved in decision making. You help your physician understand your values and the circumstances that make a difference to how you see the decision. Your physician can help you to ask questions and to further your thinking. In the end, the decision is agreeable to each of you.

What Are Informed Consent Forms For?
Informed consent forms are used to show that a decision was made with proper informed consent of the patient. They can also help the process of decision making to go well.

- **My participation in this decision**—check one:
  - [ ] I want to make the decision together with my physician.
  - [ ] I want extensive information; the physician can give an opinion but the decision is mine.
  - [ ] I want my physician to decide for me.

- **Understanding my illness**
  The name of my condition/current illness is: 
  The symptoms people with my condition often get are:

  If nothing more is done, the likely outcome of my condition (my prognosis) is:

- **Understanding my options**
  Possible approaches I could choose are:
  (Physician: list options in the table below, including no action; use additional paper if needed)
  The good and bad features of these alternatives include the following:
  (Physician: list in the table below as relevant; use additional paper if needed)

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<tr>
<th>Option</th>
<th>Good Features</th>
<th>Bad Features</th>
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Appendix. The Medical Decision Worksheet (continued)

- **Understanding my physician’s recommended option**
  (Physician: describe the approach)

- **The benefits of the recommended option**
  (Physician: list expected benefits and note how likely they are to occur)

- **The risks of the recommended option**
  Common risks include:
  (Physician: list, and note how common)
  The most serious risks include:
  (Physician: list, and note how common)

- **Learning and knowing my own mind**
  A list of items to consider:
  - Has my physician given me all the information that I want?
  - Has my physician encouraged me to raise issues and helped me to develop my thinking about this decision?
  - Have I had access to information (brochures, videos, etc) and time to think about it before I decide?
  - Have I had reasonable opportunities to talk with support groups or other people who have been in similar circumstances?
  - Has my nurse or other health care provider been available to talk things through with me?

- **My values, culture, and family participation**
  A list of items to consider:
  - Have I expressed to my physician my relevant values and relevant aspects of my culture and community?
  - Do I think that any language or communication barrier prevented a good decision?
  - Do I feel that my decision fits with my values and culture?
  - Have my family members/friend(s) been involved in this decision as much as I wanted?

- **Understanding my decision**
  My decision is:
  I understand that if I go ahead with this decision, major consequences will likely be:

  This is a reasonable decision for me because:

- **My physician will honor our decision for my medical care**
  A list of items to consider:
  - Is there significant conflict between my wishes and my physician’s professional judgment? Do we agree on the decision?
  or
  - Have I declined the recommended approach and, with a settled mind, decided to take a different one?

  If you are not comfortable with any of your responses to these items consider talking to your health care providers about it.

  Patient Signature:
  Printed Name:
  Address:
  Contact Number:

  I certify that the patient is over 18 years of age and competent to agree to (name procedure or test: )

  Physician Signature:
  Printed Name:
  Address:
  Contact Number:

  Optional:
  Witness Signature:
  Printed Name:
  Address:
  Contact Number:

  Date: